# Fluoxetine (Prozac®)

This sheet is about exposure to fluoxetine in pregnancy and while breastfeeding. This information should not take the place of medical care and advice from your healthcare provider.

***What is fluoxetine?***
Fluoxetine is a medication approved to treat depression, obsessive-compulsive disorder, Tourette's syndrome, bulimia nervosa, panic disorder, and premenstrual dysphoric disorder (PMDD). Fluoxetine has also been used to treat body dysmorphic disorder, hot sweats, posttraumatic stress disorder (PTSD), and Raynaud's phenomenon. Some brand names for fluoxetine are Prozac®, Prozac Weekly®, Rapuflux®, Selfemra®, and Sarafem®. Fluoxetine belongs to the class of antidepressants known as selective serotonin reuptake inhibitors (SSRIs).

Sometimes when people find out they are pregnant, they think about changing how they take their medication, or stopping their medication altogether. However, it is important to talk with your healthcare providers before making any changes to how you take this medication. Your healthcare providers can talk with you about the benefits of treating your condition and the risks of untreated illness during pregnancy. Some people may have a return of their symptoms (relapse) if they stop this medication during pregnancy. If you plan to stop this medication, your healthcare provider may suggest that you slowly lower the dose instead of stopping all at once. Stopping this medication suddenly can cause some people to have withdrawal symptoms.

***I take fluoxetine. Can it make it harder for me to get pregnant?***
In animal studies, fluoxetine did not have an effect on whether the animals could get pregnant. In people, fluoxetine has been studied in females having medical treatments because they were already having a hard time becoming pregnant. In these studies, those who took fluoxetine got pregnant at the same rate as those who did not take fluoxetine.

***Does taking fluoxetine increase the chance for miscarriage?***
Miscarriage is common and can occur in any pregnancy for many different reasons. A small number of studies did not find a greater chance for miscarriage when fluoxetine was used in pregnancy.

***Does taking fluoxetine increase the chance of birth defects?***
Every pregnancy starts out with a 3-5% chance of having a birth defect. This is called the background risk. Fluoxetine use is unlikely to increase the chance for birth defects.

There have been many studies looking at fluoxetine and pregnancy. There are reports on over 10,000 pregnancies exposed to fluoxetine in the first trimester. The first trimester is the time in pregnancy when major birth defects can happen. No pattern of birth defects has been found and most studies have not found an increased chance for birth defects related to fluoxetine use. Some studies have suggested an increased chance for heart defects or other birth defects. However, taking all the studies together, there is no proven risk for birth defects directly related to fluoxetine.

***Does taking fluoxetine in pregnancy increase the chance of other pregnancy related problems?***
Some complications have been reported more often if fluoxetine was used throughout the third trimester. Some studies saw a higher chance for preterm delivery (delivery before 37 weeks of pregnancy). Some studies also found babies to be a little more likely to have lower birthweight when fluoxetine was used throughout the third trimester. In some of the studies, the complications were seen more often when the medication dose used was high. Babies born early or with very low birthweight can develop health problems more easily than babies born at full term with a normal weight.

Research has also shown that when depression is left untreated during pregnancy, there could be an increased chance for pregnancy complications. This makes it hard to know if it is the medication, untreated depression (or anxiety), or other factors that may be increasing the chance for these complications.

Studies also do not agree if fluoxetine use in the second half of pregnancy might increase the chance for a serious lung problem in the baby at birth, called pulmonary hypertension. Among the studies that suggested an increased chance for pulmonary hypertension, the overall chance for this lung problem was less than 1/100 (less than 1%).

For more information about depression or anxiety, please see our fact sheets at https://mothertobaby.org/fact-sheets/depression-pregnancy/ or at https://mothertobaby.org/fact-sheets/anxiety-fact/.

***I need to take fluoxetine throughout my entire pregnancy. Will it cause withdrawal symptoms in my baby after birth?***

Some medications taken during pregnancy can cause symptoms in a newborn after delivery. These symptoms are sometimes referred to as "withdrawal".

Most babies exposed to fluoxetine in late pregnancy do not have withdrawal symptoms. However, when fluoxetine is used through the 3rd trimester, the baby could show some symptoms of withdrawal after birth. Symptoms might include: being irritable and/or jittery, crying, tight muscles, harder time breathing, unusual sleep patterns, tremors (shivers), and/or trouble eating. In most cases, these symptoms are mild and go away within weeks with no treatment, or with only supportive care. There might be a higher chance for withdrawal symptoms if other psychiatric medications are also taken with fluoxetine through pregnancy.

***Does taking fluoxetine in pregnancy affect future behavior or learning for the child?***

A few studies have looked at the development of children from age 16 months to 7 years and did not find differences between children who were exposed to fluoxetine during pregnancy and those who were not. In addition, most studies found no increase in attention deficit hyperactivity disorder (ADHD) in children exposed to SSRIs like fluoxetine during pregnancy. Most studies also find that SSRIs like fluoxetine do not appear to increase the risk of autism spectrum disorder (ASD) after accounting for the effects of maternal depression or other factors.

***Breastfeeding while taking fluoxetine:***

Most reports find no problems for breastfed babies. In a small number of cases, irritability, vomiting, diarrhea, and less sleep have been reported. One study noted slightly less weight gain in infants exposed to fluoxetine via breast milk; however, this would likely only be an issue if the infant's weight gain were already a concern. One study showed that mental and physical development was normal for infants exposed to fluoxetine via breastmilk in their first year of life.

In newborns less than two months of age, fluoxetine might have a higher chance of causing a side effect compared to older babies. The product label for fluoxetine recommends people who are breastfeeding not use this medication. But, the benefit of using fluoxetine may outweigh the risks. Your healthcare providers can talk with you about using fluoxetine and what treatment is best for you. If fluoxetine is the medication that works the best for you, breastfeeding doesn't always have to be stopped. Watch your child for any symptoms. Be sure to talk to your baby's pediatrician about any concerns you have and all your breastfeeding questions.

***If a male takes fluoxetine, could it affect fertility (ability to get partner pregnant) or increase the chance of birth defects in a partner's pregnancy?***

Fluoxetine and other SSRIs have been reported to cause some sexual side effects, such as lower sexual desire or problems with ejaculation. Studies looking at fluoxetine in a small number of males have seen that sperm quality can be affected with long-term fluoxetine use. The sperm quality was seen to improve when fluoxetine was stopped. However, while sperm quality was not as good with fluoxetine use, the level of quality was still within a normal range.

In general, exposures that fathers or sperm donors have are unlikely to increase risks to a pregnancy. For more information, please see the MotherToBaby fact sheet Paternal Exposures at http://mothertobaby.org/fact-sheets/paternal-exposures-pregnancy/.

**National Pregnancy Registry for Psychiatric Medications:** There is a pregnancy registry for people who take psychiatric medications, such as fluoxetine. For more information you can look at their website: https://womensmentalhealth.org/research/pregnancyregistry/.

**Selected References:**


- Alwan S, et al. 2016. Safety of selective serotonin reuptake inhibitors in pregnancy: a review of current evidence. CNS Drugs, 30(6):499-515.
- Andersen JT, et al. 2014. Exposure to selective serotonin reuptake inhibitors in early pregnancy and the risk of miscarriage. Obstet Gynecol, 124:655-661.
- Bandoli G, et al. 2020. Prenatal antidepressant use and risk of adverse neonatal outcomes. Pediatrics, 146(1):e20192493.
- Berard A, et al. 2017. Antidepressant use during pregnancy and the risk of major congenital malformations in a cohort of depressed pregnant women: an updated analysis of the Quebec Pregnancy Cohort. BMJ Open, 7:e013372.
- Bonari L, et al. 2004. Perinatal risks of untreated depression during pregnancy. Can J Psychiatry, 49(11):726-735.
- Burch KJ and Wells BG. 1992. Fluoxetine/norfluoxetine concentrations in human milk. Pediatrics, 89:676-677.
- Chambers CD, et al. 1999. Weight gain in infants breastfed by mothers who take fluoxetine. Pediatrics, 104(5):I1-15.
- Chambers C, et al. 2006. Selective serotonin-reuptake inhibitors and risk of persistent pulmonary hypertension of the newborn. N Engl J Med, 354(6)579-587.
- Diav-Citrin O, et al. 2008. Paroxetine and fluoxetine in pregnancy: a prospective, multicenter, controlled, observational study. Br J Clin Pharmacol, 66(5):695-705.
- Gao SY, et al. 2017. Fluoxetine and congenital malformations: a systematic review and meta-analysis of cohort studies. Br J Clin Pharmacol, 83(10):2134-2147.
- Goldstein DJ, Marvel DE. 1993. Psychotropic medications during pregnancy: risk to the fetus. JAMA, 270:2177.
- Goldstein DJ, et al. 1997. Effects of first-trimester fluoxetine exposure on the newborn. Obstet Gynecol, 89:713-8.
- Grigoriadis S, et al. 2013. The effect of prenatal antidepressant exposure on neonatal adaptation: a systematic review and meta-analysis. J Clin Psychiatry, 74(4):e309-20.
- Grigoriadis S, et al. 2019. Benzodiazepine use during pregnancy alone or in combination with an antidepressant and congenital malformations: systematic review and meta-analysis. J Clin Psychiatry, 80(4):18r12412.
- Huybrechts KF, et al. 2014. Antidepressant use in pregnancy and the risk of cardiac defects. N Engl J Med, 370:2397-2407.
- Huybrechts KF, et al. 2015. Antidepressant use late in pregnancy and risk of persistent pulmonary hypertension of the newborn. JAMA, 313(21):2142-2151.
- Isenberg KE. 1990. Excretion of fluoxetine in human breast milk. J Clin Psychiatry, 51:169.
- Jimenez-Solem E et al. 2012. Exposure to selective serotonin reuptake inhibitors and the risk of congenital malformations: a nationwide cohort study. BMJ, 2:e001148.
- Jordan S, et al. 2019. Antidepressant prescriptions, discontinuation, depression and perinatal outcomes, including breastfeeding: a population cohort analysis. PLoS One, 14(11):e0225133.

- Kaplan et al. 2017. Maternal SSRI discontinuation, use, psychiatric disorder and the risk of autism in children: a meta-analysis of cohort studies. Br J Clin Pharmacol, 83(12):2798-2806.
- Kieviet N, et al. 2015. Risk factors for poor neonatal adaptation after exposure to antidepressants in utero. Acta Paediatr, 104(4):384-391.
- Kristensen JH, et al. 1999. Distribution and excretion of fluoxetine and norfluoxetine in human milk. Br J Clin Pharmacol, 48(4):521-527.
- Levinson-Castiel R, et al. 2006. Neonatal abstinence syndrome after in utero exposure to selective serotonin reuptake inhibitors in term infants. Arch Pediatr Adolesc Med, 160:173-176.
- Louik C, et al, 2007. First-trimester use of selective serotonin-reuptake inhibitors and the risk of birth defects. N Engl J Med, 356:2675-2683.
- Lusskin SI, et al. 2018. Pharmacotherapy for Perinatal Depression. Clin Obstet Gynecol, 61(3):544-561.
- Masarwa R, et al. 2019. Prenatal exposure to selective serotonin reuptake inhibitors and risk for persistent pulmonary hypertension of the newborn: a systematic review, meta-analysis, and network meta-analysis. Am J Obstet Gynecol, 220(1):57.e1-57.e13.
- Morris R, Matthes J. 2015. Serotonin syndrome in a breast-fed neonate. BMJ Case Rep, doi:10.1136/bcr-2015-209418.
- Moses-Kolko, E.L. et al. 2005. Neonatal signs after late in utero exposure to serotonin reuptake inhibitors. Literature review and implications for clinical applications. J Am Med Assoc, 293: 2372-2383.
- Nulman I, et al. 1997. Neurodevelopment of children exposed in utero to antidepressant drugs. NEJM, 336(4):258-262.
- Nulman I, et al. 2002. Child development following exposure to tricyclic antidepressants or fluoxetine throughout fetal life: a prospective, controlled study. Am J Psychiatry, 159(11):1889-1895.
- Ornoy A. 2017. Neurobehavioral risks of SSRIs in pregnancy: Comparing human and animal data. Reprod Toxicol, 72:191-200.
- Pedersen LH, et al. 2009. Selective serotonin inhibitors in pregnancy and congenital malformations: population based cohort study. BMJ, 339:b3569.
- Rampono J, et al. 2009. Placental transfer of SSRI and SNRI antidepressants and effects on the neonate. Pharmacopsychiatry, 42(3):95-100.
- Ruchkin V, Martin A. 2005. SSRIs and the developing brain. Lancet, 365:451-453.
- Sanz E, et al. 2005. Selective serotonin reuptake inhibitors in pregnant women and neonatal withdrawal syndrome: a database analysis. Lancet, 365:482-487.
- Sjaarda LS et al. 2020. Urinary selective serotonin reuptake inhibitors across critical windows of pregnancy establishment: a prospective cohort study of fecundability and pregnancy loss. Fertil Steril, 114(6):1278-1287.
- Strain, SL. 1994. Fluoxetine-initiated ovulatory cycles in two clomiphene-resistant women. J Am J Psychiatry, 151(4):620.
- Salisbury AL, et al. 2016. The roles of maternal depression, serotonin reuptake inhibitor treatment, and concomitant benzodiazepine use on infant neurobehavioral functioning over the first postnatal month. Am J Psychiatry, 173(2):147-157.
- Sylvester C, et al. 2019. selective serotonin reuptake inhibitors and fertility: considerations for couples trying to conceive. Harv Rev Psychiatry, 27(2):108-118.
- Taddio A, Ito S, and Koren G. 1996. Excretion of fluoxetine and its metabolite, norfluoxetine, in human breastmilk. J Clin Pharmacol, 36(1)42-47.
- Wang S, et al. 2015. Selective serotonin reuptake inhibitors (SSRIs) and the risk of congenital heart defects: a meta-analysis of prospective cohort studies. Journal of the American Heart Association, 4(5)e001681.
- Wen SW, et al. 2006. Selective serotonin reuptake inhibitors and adverse pregnancy outcomes. Am J Obstet Gynecol, 194(4):961-966.

- Yang F, et al. 2017. Risk of autism spectrum disorder in offspring following paternal use of selective serotonin reuptake inhibitors before conception: a population-based cohort study. BMJ Open, 7(12):e016368.
- Yang F, et al. 2018. Prenatal paternal selective serotonin reuptake inhibitors use and risk of ADHD in offspring. Pediatrics, 141(1):e20171081.
- Yonkers KA, et al. 2009. The management of depression during pregnancy: a report from the American Psychiatric Association and the American College of Obstetricians and Gynecologists. Obstet Gynecol, 114(3):703-713.
- Yoshida, K, et al. 1998. Fluoxetine in breastmilk and developmental outcome of breastfed infants. Br J Psychiatry, 172:175-178.
- Pregnant Women with Suspected or Confirmed Influenza. Obstet Gyn, 132(4):e169-e173.